

## **REMARKS**

This Amendment responds to the non-final Office Action mailed on July 22, 2008.

Claims 1, 3-9 and 18-29 are currently pending. Claims 1, 20 and 27 have been amended. Claim 2 has been cancelled. Claims 28 and 29 have been withdrawn. In view of the following remarks, as well as the foregoing amendments, Applicants submit that this application is in complete condition for allowance in this regard.

### **Claim Objection**

Claim 1 stands objected to because of an informality. Claim 1 has been amended in a manner believed sufficient to overcome the objection.

### **Rejections of Claims under 35 U.S.C. § 102**

#### **Claims 1-4, 6, 8, 18-20, 22-25 and 27 over Brown**

Claims 1-4, 6, 8, 18-20, 22-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 2,591,046 to Brown et al. (hereinafter *Brown*). The Examiner contends that *Brown* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said tapered region.” In contrast, *Brown* discloses a syringe barrel (11) with grooves (25) that are localized over a small distance between the opposite ends of the syringe barrel (11). In particular and as apparent

from FIGS. 1-4 of Brown, the grooves (25) are localized axially over a short length near the center of the barrel (11). The grooves (25) serve to permit the stored fluid (30) to bypass the piston (16) and mix with a dry medication (29), but only when the syringe is actually used by a force applied to plunger (21) so that the piston (16) is moved relative to the barrel (11) to the location of the grooves (25). Hence, the grooves (25) are intentionally located only near a central position so that, as the piston (16) is moved by force applied to the plunger (21), the grooves (25) are eventually available to the stored fluid (30) as flow channels to permit the fluid (30) to flow past the piston (16) and mix with the dry medication (29). Otherwise, the grooves (25) would not block the flow of the stored fluid (30) past the piston (16) to reach the dry medication (29). The grooves (25) in *Brown* are not contacted by the fluid in the state in which the syringe is stored (FIG. 2). The syringe in *Brown* is not capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Brown* fails to disclose “said axial grooves extending substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said tapered region” and fails to disclose a syringe capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing, *Brown* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6, 8, 18-20, 22-25 and 27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Brown*. Applicants note that the Examiner has failed to state a *prima facie* of obviousness for dependent claims 3, 4, 6, 8, 18-20, 22-25 and 27. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 3, 4, 6, 8, 18-20, 22-25 and 27.

*Claims 1-4, 6, 8, 18-20, and 22-27 over Bachynsky*

Claims 1-4, 6, 8, 18-20, and 22-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,971,953 to Bachynsky (hereinafter *Bachynsky*). The Examiner contends that *Bachynsky* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

As mentioned above, independent claim 1 sets forth “said axial grooves extending substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said tapered region.”

In contrast, *Bachynsky* discloses a syringe barrel (11) with grooves (30) that are localized over a small distance between the openings at the opposite ends of the barrel (11). In particular, the grooves (5) are localized axially near the center of the barrel (11). The grooves (30) serve to permit the stored fluid (23) to bypass the piston (32) and mix with a dry medication (24), but only when the syringe is actually used by a force applied to plunger (40) so that the piston (32) is moved relative to the barrel (11) to the location of the grooves (30). Hence, the grooves (30) are

intentionally located only near a central location relative to the ends of the barrel (11) so that, as the piston (32) is moved by the force applied to the plunger (40), the grooves (30) are eventually available to the stored fluid (23) as flow channels to permit the fluid (23) to flow past the piston (32) and mix with the dry medication (24). Otherwise, the grooves (30) would not block the flow of the stored fluid (23) past the piston (32) to reach the dry medication (24). Hence, the grooves (30) fail to extend from approximately the opening at the one end of the barrel (11) through which the piston (32) is inserted to approximately the tapered end of the barrel (11) that is near the needle (18). The grooves (30) in *Bachynsky* are not contacted by the fluid in the state in which the syringe is stored (FIG. 1). The syringe in *Bachynsky* is not capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Bachynsky* fails to disclose “said axial grooves extending substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said tapered region” and fails to disclose a syringe capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing, *Bachynsky* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6, 8, 18-20, and 22-27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Bachynsky*. Applicants note that the Examiner has failed to state a *prima facie* case of obviousness for dependent claims 3, 4, 6, 8, 18-20, and 22-27. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 3, 4, 6, 8, 18-20, and 22-27.

*Claims 1-4, 6-8, 18-20, 22-25, and 27 over Reinhard*

Claims 1-4, 6-8, 18-20, 22-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,788,670 to Reinhard et al. (hereinafter *Reinhard*). The Examiner contends that *Reinhard* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending substantially parallel to said longitudinal axis from a first location on said inwardly-facing surface proximate to said first opening to a second location on said inwardly-facing surface proximate to said tapered region.”

In contrast, *Reinhard* discloses a syringe barrel (1) with grooves (5) that are localized over a small distance between the openings at the opposite ends of the syringe barrel (1). In particular, the grooves (5) are localized axially near the center of the barrel (1). The grooves (5) function to permit the stored liquid in chamber (3a) to bypass the piston (11) and mix with a dry component in chamber (2a), but only when the syringe is actually used by a force applied to plunger (9) so that the piston (11) is moved relative to the barrel (1) to the location of the grooves (5). See col. 6, lines 23-42. Hence, the grooves (5) are intentionally localized so that, as the

piston (11) is moved by the force applied to the plunger (9), the grooves (5) are eventually available to the stored liquid as flow channels to permit the liquid in chamber (3a) to flow past the piston (11) and mix with the dry component in chamber (2a). Otherwise, the grooves (5) would not block the flow of the stored liquid past the piston (11) to reach the dry component in chamber (2a). Hence, the grooves (22) fail to extend from approximately the open end of the barrel (1) through which the piston (11) is inserted to approximately the tapered end (near the terminus of the lead line for reference numeral (4) of the barrel (1). The grooves (22) in *Reinhard* are even contacted by the fluid in the state in which the syringe is stored (FIG. 1). The syringe in *Reinhard* is not capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing.

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Reinhard* fails to disclose “said axial grooves extending substantially parallel to said longitudinal axis from a first location proximate to said first opening to a second location proximate to said tapered region” and fails to disclose a syringe capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing, *Reinhard* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 3, 4, 6-8, 18-20, 22-25, and 27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by

*Reinhard.* Applicants note that the Examiner has failed to state a *prima facie* case of obviousness for dependent claims 3, 4, 6-8, 18-20, 22-25, and 27. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 3, 4, 6-8, 18-20, 22-25, and 27.

*Claims 1-3, 6-8, 18-20, and 22-27 over Nissho*

Claims 1-3, 6-8, 18-20, and 22-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by JP08-57051 to Nissho Co. Ltd. (hereinafter *Nissho*). The Examiner contends that *Nissho* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

*Nissho* fails to disclose “a plurality of axial grooves defined in said inwardly-facing surface” of the syringe sidewall. The Examiner merely states in the Office Action that the presence of “grooves” is inherent in *Nissho* because “the inner surface of the syringe is roughened.” The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support his determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Here, the Examiner fails to provide such a basis in fact and merely supplies a conclusion. In the absence of factual evidence, the Examiner fails to set forth any line of reasoning whatsoever on page 4 of the Office Action to support the allegation of inherency. Specifically, the Examiner fails to provide an objective line of reasoning as to what disclosure in *Nissho* would lead a person having ordinary skill in the art to necessarily conclude that the roughening in *Nissho* is

necessarily provided by axial grooves as set forth in Applicants' claim 1. For these reasons alone, independent claim 1 is patentable.

Because claims 3, 4, 6-8, 18-20, and 22-27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Nissho*. Applicants note that the Examiner has failed to state a *prima facie* of obviousness for dependent claims 3, 4, 6-8, 18-20, and 22-27. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 3, 4, 6-8, 18-20, and 22-27.

*Claims 1-8 and 18-27 over Wyatt*

Claims 1-8 and 18-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pub. No. 2005/0221035 to Wyatt (hereinafter Wyatt). The Examiner contends that Wyatt shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Similar to *Nissho*, *Wyatt* fails to disclose “a plurality of axial grooves defined in said inwardly-facing surface” of the syringe sidewall. The Examiner merely states in the Office Action that the presence of “grooves” is inherent in *Wyatt* because “the inner surface of the syringe is roughened.” The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support his determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Here, the Examiner fails to provide such a basis in fact and merely supplies

a conclusion. In the absence of factual evidence, the Examiner fails to set forth any line of reasoning whatsoever on page 4 of the Office Action to support the allegation of inherency. Specifically, the Examiner fails to provide an objective line of reasoning as to what disclosure in *Wyatt* would lead a person having ordinary skill in the art to necessarily conclude that the roughening in *Wyatt* is necessarily provided by substantially parallel axial grooves. The roughening techniques described in paragraphs 10-12 of *Wyatt* provide a surface treatment with randomly arranged features, not substantially parallel axial grooves. For these reasons alone, independent claim 1 is patentable.

Because claims 2-8 and 18-27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by Nissho. Applicants note that the Examiner has failed to state a prima case of obviousness for dependent claims 2-8 and 18-27. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 2-8 and 18-27.

**Rejection of Claims under 35 U.S.C. § 103(a)**

***Claims 5 and 21***

Claims 5 and 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Nissho*. Applicants submit that dependent claims 5 and 21 are patentable for at least the same reasons as independent claim 1. To establish a prima facie case of obviousness, the prior art references being combined must teach or suggest all the claim limitations. Furthermore,

dependent claims 5 and 21 each recites a unique combination of elements not disclosed or suggested by *Nissho*.

*Claim 9*

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown*, *Bachynsky*, *Reinhard*, *Wyatt*, or *Nissho* in view of U.S. Patent No. 4,846,796 to Carrell et al. (hereinafter *Carrell*). Applicants submit that dependent claim 9 is patentable for at least the same reasons as independent claim 1. To establish a *prima facie* case of obviousness, the prior art references being combined must teach or suggest all the claim limitations. Furthermore, dependent claim 9 recites a unique combination of elements not disclosed or suggested by the combination of *Brown*, *Bachynsky*, *Reinhard*, *Wyatt*, or *Nissho* with *Carrell*.

**Response to the Examiner's Response to Arguments relating to Brown, Bachynsky, and Reinhard**

The Examiner contends on page 6 of the Office Action “‘approximately’ is a relative term and, consequently, is very broad. Syringes are relatively small devices designed to be hand held and therefore the examiner maintains that all the parts of a syringe can be considered to be approximately near another part of a syringe.” Applicants disagree with these contentions for the same reasons as in their June 27, 2008 Response, as well as additional rebuttal arguments as added below in response to the Examiner’s additional comments in the instant Office Action.

During examination of a patent application, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain

meaning unless the plain meaning is inconsistent with the specification. The plain meaning of a claim term is the ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application.

According to its plain meaning, the term “approximate” in claim 1 is ordinarily and customarily defined as “close together but not exact.” *See* The American Heritage Dictionary, 3<sup>rd</sup> Ed. (Houghton Mifflin 1997). Despite the Examiner’s remarks to the contrary, the small size of a syringe is totally unrelated to the position of the grooves relative to the first opening and the position of the axial grooves relative to the tapered region. Claim 1 sets forth that the axial grooves extend from approximately (in other words, close to but not exactly at) the first opening in the barrel to approximately (in other words, close to but not exactly at) the tapered region of the barrel.

Words of approximation, such as “generally” and “substantially”, are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to the specified parameter. Anchor Wall Systems v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1311 (Fed. Cir. 2003); Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1367 (Fed. Cir. 2001) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)); see, e.g., Andrew Corp v. Gabriel Elecs, Inc., 847 F.2d 819, 821-22 (Fed. Cir. 1988) (noting that terms such as “approach each other,” “close to,” “substantially equal,” and “closely approximate” are ubiquitously used in patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts).

In claim 1, the use of the term “approximately” is used to avoid a strict numerical boundary that one end of each groove be located exactly at the first open end of the barrel and the opposite end of each groove be located exactly at the tapered region of the barrel. Hence, after the claim is properly construed, the issue for interpreting the disclosure in the prior references applied by the Examiner in the Office Action is not the absolute positions of the parts of a small syringe but, instead, the relative positions of the parts of a small syringe to determine whether or not these parts are approximate (close but not exactly at).

In *Brown*, the grooves (25) are localized over a small distance centrally between the opening at the one end of the barrel (11) into which the piston (16) is inserted and the tapered end of the barrel (11) that is near the needle (15). Hence, the grooves (25) fail to extend from approximately (close but not exactly at) the opening at the one end of the barrel (11) through which the piston (16) is inserted to approximately (close but not exactly at) the tapered end of the barrel (11) that is near the needle (15).

In *Bachynsky*, the grooves (5) are localized axially near the center of the barrel (11). Hence, the grooves (5) fail to extend from approximately (close but not exactly at) the opening at the one end of the barrel (11) through which the piston (32) is inserted to approximately (close but not exactly at) the tapered end of the barrel (11) that is near the needle (18).

In *Reinhard*, the grooves (5) are localized over a small distance centrally located between the unlabeled opening at the one end of the syringe barrel (1) through which the piston (8) is inserted and the tapered end (near the terminus of the lead line for reference numeral (4)) of the barrel (1). Hence, the grooves (22) fail to extend from approximately (close but not exactly at) the open end of the barrel (1) through which the piston (8) is inserted to approximately (close but

not exactly at) the tapered end (near the terminus of the lead line for reference numeral (4)) of the barrel (1).

The Examiner states in the July 22, 2008 Office Action that “the case law cited by the applicant is irrelevant because ‘approximately’ is not instantly being used to modify a range or numerical boundary as was the issue in the cited cases.” Applicants disagree. The phrase “numerical boundary” does not mean that the use of words of approximation is limited literally to a number or a numerical range. As used by Applicants and by the courts, the phrase “numerical boundary” means exactness. In Anchor Wall Systems v. Rockwood Retaining Walls, Inc., the phrase being modified by the word of approximation “generally” was “parallel”. In this case, the court held that exact parallelism sufficient, but not necessary, to meet the limitation of the claim term “generally parallel.” In Ecolab, Inc. v. Envirochem, Inc., the phrase being modified by the word of approximation “substantially” was “uniform”. The court held that “[i]n this case, ‘substantially’ avoids the strict 100% nonuniformity boundary.” The holdings in these cases are consistent with the Applicants usage and with the understanding of a person having ordinary skill in the art.

Generally, Applicants’ claim 1 is also non-obvious over *Brown, Bachynsky*, and *Reinhard*, either alone or in combination, because they would not work for their intended purpose if the axial grooves were modified, as suggested by the Examiner, to extend along a longitudinal axis from “approximately said first opening to approximately said tapered region.” As explained above, none of these particular references teaches axial grooves of this length. In each instance, the absence of this teaching is a product of the disclosed use of the syringes. Specifically, the axial grooves in each reference represent bypass flow channels that permit

components of a mixture to combine when the mixture is injected into a patient. Otherwise, the components of the mixture are isolated from each other until use. Were the length of the grooves somehow extended from “approximately said first opening to approximately said tapered region,” as set forth in claim 1, then the components would never be isolated from each other inside the syringe and would readily mix. The primary objective of the syringe in each of these references is to isolate the components of the mixture until use. In each instance, the syringe would be rendered inoperative for its intended purpose by a modification of the length of the grooves.

The Examiner states on page 7 of the Office Action that “if the prior art structure is capable of performing the intended use, then it meets the claim.” Applicants disagree. Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. As amended, the axial grooves are “configured to be contacted by the fluid and to reduce the void formation in the fluid”. This is a fundamental characteristic of the claimed syringe and is being relied upon by the Applicants during prosecution to distinguish the claimed invention from the prior art. Applicants submit that the grooves in the syringes of *Brown*, *Bachynsky*, and *Reinhard* are not capable of reducing void formation because, for among other reasons, their limited extent along the inwardly facing surface of the sidewall in each reference. A large portion of the sidewall in each of these references lacks grooves and, as such, would not be capable of reducing void formation in such a fluid.

*Brown* dispenses a mixture of a liquid and powder. *Bachynsky* dispenses a mixture of a liquid diluent and a dry medicine. *Reinhard* dispenses a mixture of a stored liquid in chamber (3a) and a dry component in chamber (2a). None of these references discloses that the subject

syringe could be used to dispense a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed before dispensing.

### Conclusion

Applicants have made a bona fide effort to respond to each and every requirement set forth in the Office Action. In view of the foregoing remarks, this application is submitted to be in complete condition for allowance. Accordingly, a timely notice of allowance to this effect is earnestly solicited. In the event that any issues remain outstanding, Applicants invite the Examiner to contact the undersigned to expedite issuance of this application.

Applicants do not believe any fees are due in connection with filing this communication. If, however, any petition or additional fees are necessary because of this communication, the Commissioner is hereby authorized to charge any under-payment or fees associated with this communication or credit any over-payment to Deposit Account No. 23-3000.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

/William R. Allen/

William R. Allen  
Reg. No. 48,389

2700 Carew Tower  
441 Vine Street  
Cincinnati, Ohio 45202-2917  
(513) 241-2324 (voice)  
(513) 241-6234 (facsimile)